Evaluation of clinical performance of a new molecular point-of-care assay for detecting *C. difficile*

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Background

Clostridioides difficile (*C. difficile*) is a significant cause of healthcare-associated infections, leading to conditions ranging from mild diarrhea to severe colitis. Accurate and timely diagnosis of *C. difficile* infection (CDI) is critical for patient management and infection control. Traditional diagnostic methods face challenges, including delayed results and the need for specialized laboratory facilities. Point-of-care (POC) assays offer a promising alternative, potentially enabling rapid and accurate diagnosis.

We evaluated the clinical performance of a new molecular POC assay, Vivalytic *C. difficile* (Figure 1).

Figure 1: Vivalytic one Analyzer and Vivalytic *C. difficile* cartridge.

Methods

124 liquid or soft human stool samples from two study sites were analyzed.
At MVZ Labor Dr. Limbach & Kollegen GbR in Heidelberg, Germany, 44 samples (21 positive and 23 negative) were tested.
At aprimeo diagnostics GmbH in Pfungstadt, Germany, 80 samples (39 positive and 41 negative) were tested. A total of 122 valid samples were included in the analysis.

The RIDA®GENE Clostridium difficile assay was used as reference method (R-Biopharm AG). Discrepant results were resolved with Allplex™ GI-Bacteria(I) assay (Seegene) and *Xpert® C. difficile BT* assay (Cepheid).

The Vivalytic *C. difficile* test combines rapid and precise testing at the point of care.

- Time to result: Early finish 35 min; max. 50 min
- Hands on time: 2 min
- Fully automated

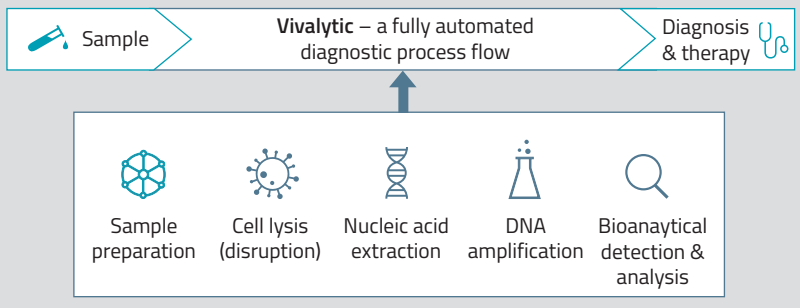

Figure 2: The fully automated process chain of the Vivalytic analyzer ensures maximum safety and rapid results.

Results

The Vivalytic *C. difficile* assay showed 12 initial discrepant results compared to the reference tests. Upon retesting these samples with the reference methods, 5 discrepancies remained: 3 false positives and 2 false negatives (Table 1 & 2). The assay demonstrated a Positive Percent Agreement (PPA) of 96.61 % and a Negative Percent Agreement (NPA) of 95.24 % (Table 3).

Table 1: Performance data of Vivalytic *C. difficile* test for *C. difficile* at Limbach in comparison to the reference test.

		Reference/third-party test (RIDA®GENE/Cepheid)		
		Positive	Negative	Total
Vivalytic *C. difficile*	Positive	21	2	23
	Negative	0	20	20
	Total	21	22	43
		Concordance	**Sensitivity (PPA)** (95 %-width of CI)	**Specificity (NPA)** (95 %-width of CI)
		95.34 %	100.0 % (83.89 – 100.0 %)	90.91 % (70.84 - 98.89 %)

Table 2: Performance data of Vivalytic *C. difficile* test for *C. difficile* at aprimeo in comparison to the reference test.

		Reference/third-party test (RIDA®GENE/Cepheid)		
		Positive	Negative	Total
Vivalytic *C. difficile*	Positive	36	1	37
	Negative	2	40	42
	Total	38	41	79
		Concordance	**Sensitivity (PPA)** (95 %-width of CI)	**Specificity (NPA)** (95 %-width of CI)
		96.20 %	94.74 % (82.25 – 99.36 %)	97.56 % (87.14 - 99.94 %)

Table 3: Overall results of the clinical performance evaluation of *C. difficile* in comparison to the reference tests.

		Reference/third-party test (RIDA®GENE/Cepheid)		
		Positive	Negative	Total
Vivalytic *C. difficile*	Positive	57	3	60
	Negative	2	60	62
	Total	59	63	122
		Concordance	**Sensitivity (PPA)** (95 %-width of CI)	**Specificity (NPA)** (95 %-width of CI)
		95.90 %	96.61 % (88.29 % - 99.59 %)	95.24 % (86.71 % - 99.01 %)

Conclusion

The Vivalytic *C. difficile* assay exhibits high sensitivity and specificity, making it a viable option for rapid diagnosis of *C. difficile* infection. Its implementation could enhance clinical decision-making and infection control practices by providing timely results without the need for specialized laboratory infrastructure.

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